

MEDICAL COLLEGE OF OHIO

Subject: RESPONSIBLE CONDUCT OF RESEARCH AND
OTHER SCHOLARLY ACTIVITIES

Policy No.: 03-012

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I. Preamble

This policy describes the standard of practice required for the conduct of research and other scholarly activities at The Medical College of Ohio (MCO). It is intended to complement, but is independent of, existing MCO policies, sponsoring agency policies, and federal regulations governing certain aspects of the conduct of research including, but not limited to, human subjects research, animal use, radiation, biosafety, conflict-of-interest, and hazardous chemicals. A separate MCO Policy (02-003) entitled "Academic and Scientific Misconduct", which is mandated by federal regulations describes how MCO handles issues of Misconduct. MCO complies with all applicable laws and regulations (See appendix). The present policy is based on three important principles:

1. The Medical College of Ohio is obligated to protect and foster the academic freedom and intellectual integrity of all members of the MCO community in their pursuit of knowledge;
2. The Medical College of Ohio is accountable to outside funding and regulatory entities that support, and/or regulate, the research and scholarship of its faculty; and
3. Each scholar has responsibility for the accuracy and validity of his/her own work and that of junior co-investigators, fellows, and students working under his/her tutelage. Each scholar shares this responsibility with colleagues with whom she/he establishes collaborative relationships.

II. Areas of Applicability

This document applies to research in all areas of intellectual inquiry. A separate section addresses issues specific to scientific research. This Policy is intended to heighten awareness of potential ethical issues and to instruct individuals regarding appropriate procedures for resolving and documenting ethics-related matters. The focus is on the individual scholar; the purpose is to emphasize that his/her responsibility includes a duty to maintain high scholarly and ethical standards, and a commitment to instill those standards in co-investigators and trainees.

Scientific inquiry, scholarly contributions, creativity, and academic accomplishment can take many forms and may vary among disciplines. The issues addressed by this Policy are essential to all scholarly activity within the MCO

community. Scholarly responsibility, quality of scholarly activity, accuracy of scholarly contributions and their sources, responsible authorship, and provision for training in ethics of each discipline are issues inherent to all areas. The implications of this Policy apply as fully to the scholar who co-authors a textbook in his/her discipline as to the laboratory scientist who reports a biological discovery, or the clinician who publishes the results of a prospective study of a patient-oriented research problem.

This Policy addresses the following concerns:

1. the scholar's authority and responsibility for research activities;
2. the establishment of the quality of research;
3. authorship of publications, including multi-author publications and requisites for authorship;
4. the supervision of Trainees¹;
5. the education of Trainees in research ethics and integrity;
6. documentation of, access to, and retention of scientific research protocols and data; and
7. the social responsibility of the scholar.

III. The Conduct of Research and Scholarship

A. Authority and Responsibility for Research Activities

Each Department Head² is responsible for assuring that each trainee has a specific faculty Research Director³. This responsibility should not be construed as carrying rights of authorship, consultation, or approval of manuscripts prior to publication.

B. Establishing the Quality of Research

1. Primary assurance of the quality of research stems from the scholarly qualifications of individual faculty members. All faculty members are ultimately responsible for the scholarly character, accuracy, and reliability of their own research and for that conducted under their supervision, no matter who actually performs the work or under what circumstances. Each scholar is also responsible for the integrity and originality of his/her own research. The most effective single process for ensuring research of high quality is peer review, both formal and informal. Informal review occurs through departmental and interest-group seminars and research discussion groups. Each school, department, or program should encourage such informal review procedures. Formal review will be accomplished by the existing national peer review process charged with the task of evaluation of the merit and relevance of research. (Examples of national peer review include review of a grant proposal by an NIH study section or peer review of a manuscript submitted for publication.)

2. Faculty should establish an intellectual atmosphere that promotes high academic and moral standards and in which issues of social responsibility and professional ethics are addressed.

3. MCO's formal policy governing investigations of misconduct in research ("Academic and Scientific Conduct" MCO Policy #02-003) should be followed when allegations of research improprieties have been made. That document, which is incorporated here by reference, should be on file in the office of Research Director and faculty member and should be distributed to all members of the research team.

C. Authorship of Publications

1. By virtue of the multiplicity of sources of concepts and information upon which any piece of scholarship is based, it is essential that proper attribution be emphasized in the presentation of ideas and the publication of manuscripts.

2. Authorship should be granted to, and only to, those persons who have made appropriate contributions to the conceptualization, design, execution, or interpretation of the work reported. Individuals who have made lesser contributions should be acknowledged, but do not necessarily warrant authorship. The principal author should determine whether such individuals should be listed as authors. Acquisition of funding, collection of data, or general supervision of the research group, by themselves, do not justify authorship. In some fields, written permission may be required for acknowledgments. In factual or scientific reports, authors should take care to cite relevant data including those which do not support the hypothesis being presented. It is an author's responsibility to be familiar with and to cite other publications relevant to his/her work. It is unethical, and harmful to the scholarly endeavor, to submit the work of others, in whole or in part, as one's own, to fabricate research results, or to suppress or alter information. (Modified from "Ethical Guidelines for Publication of Research", *Endocrine Reviews*, 10:1, 1989 and "Authorship and Other Credits", N. Fotion and C.C. Conrad, *Annals of Internal Medicine*,

100:592, 1984.) Authors who wish to cite information learned personally or from unpublished materials should obtain written permission from the source. The order of authorship should be a joint decision of the coauthors.

3. It is inappropriate to submit manuscripts, or reports of the same research to more than one publisher unless the action is authorized by the editors of each publication or multiple submission is the accepted standard of practice in a discipline/field. Preliminary accounts or abstracts of work already published should be referenced in any complete report of that work.

4. Multi-authorship raises issues such as criteria for inclusion as an author, ability of each author to evaluate all aspects of a study, and sequence of listing of authors. Authors should discuss these issues openly before initiating a multi-author project and repeatedly during the course of such work. The corresponding or primary author is charged with the responsibility of coordinating the completion and submission of the work, and for assuring that the contributions of all collaborators are appropriately recognized. All authors should approve the final version of a manuscript and should be prepared to take public responsibility for the work. "An author who is willing to take credit for a paper must also bear responsibility for its contents." ("On Being a Scientist: Responsible Conduct in Research", National Academy Press, Washington, D.C., 1995, pg. 14).

5. Each author or co-author is responsible for composing, reviewing, and verifying those portions of a manuscript, publication, or presentation that represent his/her contribution. Each author should sign a statement of verification attesting to the authenticity of the manuscript. The signatures should be appended to the final manuscript. All co-authors are entitled to make appropriate copies of a manuscript, including figures and appended documents.

D. Supervision of Trainee Scholarship

1. MCO's responsibility to educate and prepare Trainees to enter society and to practice their disciplines with high ethical standards does not cease with formal course work. The Medical College of Ohio and its faculty have an obligation to the academic community, the public, and the Trainee to ensure that all Trainees engage responsibly in scholarship and research, using the highest professional standards.

2. Research Directors and Department Heads share responsibility for guaranteeing an open and equitable research environment that protects the interests of Trainees, assistants and other vulnerable research personnel. They should ensure that Trainees are given due recognition for original work, that demands made upon Trainees are reasonable, and that they are treated in interpersonal relationships with the same professional courtesy granted peer colleagues. Avenues must be available for Trainees who feel their supervision or training is inadequate to bring this to the attention of the Research Director or, if necessary, to the appropriate Department Head.

3. Research Directors should meet regularly with Trainees and other collaborators to review their work and progress.

4. Research Directors should serve as role models and maintain the highest standards in performance of research. They should encourage Trainees to be open and to share ideas and information with other members of the scholarly community. They should ensure that the experience of their Trainees serves to prepare them to become independent scholar and researchers.

5. The number of Trainees each Research Director is responsible for should be small enough that close interaction is possible for scientific exchange as well as oversight of research at all stages.

E. Education of Trainees in Research Ethics and Integrity

1. Ethical issues and questions in the conduct of scholarship should be made an integral part of the education of all Trainees. Research Directors are responsible for establishing a training environment in which value-related issues are discussed. The Research Director should expect and foster a familiarity with ethics as related to scholarship. The goals should be to teach Trainees how to identify ethical issues and how to address the common ethics-related questions that arise in the course of investigation and publication.

2. Department Heads, division chiefs, and program directors are responsible for fostering the teaching of ethics within their academic units. An ethics component of the curriculum should provide Trainees and faculty with the intellectual tools and interactional skills to apply ethical thinking to everyday problems encountered in their research. Ethical issues, concepts and theoretical grounding should be introduced as part of the orientation of all Trainees.

F. The Social Responsibility of the Scholar

Scholars have an obligation to ensure that scholarship is not misused and that it does not become a tool for abuse. Scholars are more likely than others to know the limits and conditions of current knowledge in their own fields, and the

problematic aspects of using this knowledge to make public policy. Scholars have a right and a responsibility to make their voices heard when their scholarship and their contribution to society are being misquoted, misunderstood, or misapplied. (Adapted from S.J. Bird, President's Remarks, "Professional Responsibility", AWIS Magazine, 20:2, 1991.) Scholars are also responsible for being familiar with all MCO policies related to research, including the Intellectual Property Policy (#03-003), the Academic and Scientific Misconduct Policy (#02-003), the Conflict-of-Interest Policy (#03-005), the Sponsored Projects Policy (#03-001), the Human Subjects in Research Policy (02-001), the Animal Subjects in Research Policy (#03-007) and this Policy.

G. Peer Review and Privileged Information

Peer review can be defined as expert critique of a scholarly treatise, such as a manuscript, a grant/contract proposal, a research protocol, or of an entire research program, as in a site visit. Peer review is an essential component of the conduct of scientific research and other scholarly activity. Decisions made in the peer review process must be based on thorough, fair, and objective evaluations by recognized experts. Therefore, although it is often difficult and time-consuming, scientists have an obligation to participate in the peer review process and, in doing so they make an important contribution to science.

Peer review must be objective. It should thus be based solely on scholarly evaluation of the material under review within the context of published information and should not be influenced by scientific information not publicly available.

All material reviewed must be considered to be privileged information. It should not be used to the benefit of the reviewer unless it previously was made public. It should not be shared with anyone unless necessary to the review process, in which case the names of those with whom the information was shared should be made known to those managing the review process. Material under review should not be copied and retained or used in any manner by the reviewer unless specifically permitted by the journal or reviewing organization and the author of the material.

Privileged or confidential information may also be obtained by an individual as a result of a collaboration with other investigators, both within MCO and outside of MCO, or when involved in research projects sponsored by corporate entities that share some of their confidential information or trade secrets in order to facilitate the research project. This information obtained from corporate entities generally is protected by a written confidentiality agreement between the company and the investigator and, at times, MCO. All parties to such an agreement are expected to adhere strictly to the responsibilities imposed by the agreement. Even when information exchanged between investigator collaborators or between investigators and research sponsors is not protected by a written confidentiality agreement, investigators should consider that information to be privileged, unless they know that the information has been previously published, or the owner of the information makes it clear that the information is not privileged or confidential.

IV. The Conduct of Scientific Research

The following paragraphs refer specifically to scientific research and serve as an addendum to the broader guidelines described above.

A. Authorship and Responsibility for Scientific Research Activities

Each Department Head or program director is responsible for assuring that:

- (1) every laboratory or research unit has a designated Research Director, and
- (2) that each Trainee has a specific faculty research preceptor.

B. Establishing the Quality of Scientific Research

1. The Research Director is responsible for assuring close personal supervision of the research of students including the design of research protocols, approval by appropriate committees, data gathering and recording, statistical analysis, interpretation of results, preparation of manuscripts, submission and revision of manuscripts for publication, and presentations at scholarly meetings.

2. The Research Director is also responsible for informing each new staff person, Trainee, or junior investigator of applicable federal, state and institutional regulations for conduct of studies involving humans, animals, radioactive and other hazardous materials, and recombinant DNA. The Research Director is also responsible for informing personnel in their laboratories about existing MCO policies, including this one. The Research Director is also responsible for explaining and discussing the relevant requirements for the responsible conduct of research with Trainees and visiting scientists in the laboratory, and to ensure that such requirements are met.

3. The distinction between intellectually-driven inquiry and commercially-targeted research is sometimes vague. Many respected faculty are committed to developing and to studying tools, techniques and processes whose primary purpose is to promote the health or welfare of society in areas having potential commercial value. The Research Director is responsible for assuring that such investigations meet the same standards of quality and reproducibility as investigations of a more basic nature. Furthermore, any faculty member that has financial interests in a company sponsoring his/her research should disclose such financial interests to his/her Department Head, in accordance with the MCO Conflict-of-Interest Policy (#03-005) to avoid the potential for conflicts-of-interest, or the appearance thereof. When there is a possibility that Trainees may be involved in research sponsored by a commercial entity, special care must be taken to ensure that the academic welfare and freedom of the Trainees is protected. Frequently research contracts with commercial sponsors contain confidentiality and/or publication provisions that limit the ability of laboratory personnel, including Trainees, to freely communicate the results of their research. Student participation in projects with such restrictions has a potential to affect timely dissemination of results of a student's research in the form of a dissertation or other publications.

4. In keeping with the principle of fostering reproducibility in science, and in the absence of patent or copyright considerations, novel compounds and reagents used for experiments should be made available, or appropriately described means for obtaining these should be given, to other competent members of the research community upon request and after execution of a Material Transfer Agreement. Investigators should have the latitude to make a fair and balanced response to requests for all research substances, including novel compounds and reagents.

5. Clinical research requires special attention to issues of informed consent and confidentiality. Because patients have a right to assume that decisions about their treatments are made in their best interests, the physician-investigator should disclose all significant alternatives and risks to patient-subjects so that they can make an informed judgment about participation in a study. Signed copies of informed consent must be placed in the patient's clinical records as well as with research records. Clinical research records generally remain the property of MCO, and the Department Head of each Principal Investigator conducting clinical trials is responsible for maintenance of the records associated with those trials. Faculty members, as well as the company which sponsors the clinical trials, may make copies of the records upon departure from MCO, but the original records must remain at MCO under the custodial care of the Principal Investigator, or in his/her absence, his/her Department Head.

C. Access to and Retention of Scientific Research Protocols and Data (Also See Appendix)

1. Both the Research Director and MCO have responsibilities and, hence, rights concerning access to, use and maintenance of original research data. ("Ownership of Research Data". Estelle A. Fishbein, *Academic Medicine*, 66:129, 1992 and "Workshop Summary". L.J. Rhoades, *Data Management in Biomedical Research: Report of a Workshop*, USPHS, pp. 2-9, 1990.) In general, since grants/contracts are between MCO and the sponsoring agency, not between the principal investigator and the sponsoring agency, research data are owned by MCO, not the principal investigator or the researcher producing the data. Consistent with the precepts of academic freedom and intellectual integrity, data management, including the decision to publish, is the responsibility of the Research Director.

2. Each Research Director is ultimately responsible for the maintenance and proper retention of research records. These records should include sufficient detail to permit examination for the purposes of replicating the research, responding to questions that may result from unintentional error, alleged misinterpretation or alleged scientific misconduct, establishing their authenticity, and confirming the validity of the conclusions. In the absence of unambiguous, easily retrievable primary experimental data, honest errors may be mistaken for misconduct.

3. Each Research Director should maintain a laboratory manual, either in paper or electronic format, that describes all major procedures. Correspondence with institutional review committees and records of the use of controlled substances and radioactive materials should be maintained as part of the research record in accordance with governmental, regulatory, and MCO policies.

4. A standardized system of data organization should be adopted and should be communicated to all members of a research group and to the appropriate administrative person. The appropriate administrative person should be determined by the sub-unit.

5. Where feasible, all original primary data are to be retained by the Research Director or by his or her designee. Accepted practices for retaining data vary among disciplines and depend on the perishability nature and logistics of retaining each type of data. Each investigator should treat data properly to ensure authenticity, reproducibility, and validity and to meet the requirements of relevant grants and other agreements concerning the retention of data. Primary data should be reserved for a reasonable duration to ensure that any questions raised by the researcher, colleagues, or readers of any published results can be answered. It is recommended that, where feasible, data be retained for seven years; in circumstances where there are no federal or other requirements such as those referred to in the Appendix, sub-units of MCO may wish to establish uniform standards and procedures for retention and destruction of data. Data should not be destroyed without proper notification of and

approval by an appropriate administrative person. In unusual cases (e.g., data used for a patent application filed by or on behalf of MCO), it may be necessary for original data to be kept at MCO. Data associated with potentially patentable inventions or discoveries should be signed and dated by the preceptor at the time they are entered into notebooks or maintained by other methods of retention in the event the results are questioned. Departing investigators or Trainees may take copies of notebooks or other data for further work, but the originals must be kept at MCO by the Research Director.

6. In the event the Research Director leaves MCO, an Agreement of Disposition of Research Data may be negotiated by the scholar and the Department Head or dean to allow the scholar's data, notebooks, and other data retention materials (other than clinical research records) to be transferred to the scholar's new institution. Consistent with the same precepts, and to fulfill its obligations to funding sources and others, MCO will ensure in such agreements access to the transferred data for purposes of review. In unusual cases (e.g., data used for a patent application filed by or on behalf of MCO) it may be necessary for original data to be kept at MCO. In such cases an individual written agreement shall be signed which preserves the scholar's right to access and copy (where practical) such data. In cases of multi-institutional studies, the institution of the primary study director is ultimately responsible for guaranteeing appropriate access to, use of, and retention of original data.

D. Collaborations

Research collaborations frequently facilitate progress and generally should be encouraged. It is advisable that the ground rules for collaborations, including data management and eventual authorship issues be discussed openly among all collaborators from the beginning. Whenever collaborations involve the exchange of materials between MCO investigators and investigators outside of MCO, a Material Transfer Agreement (MTA) or other formal written agreement(s) may be necessary. Information regarding such formal agreements may be obtained from Research & Grants Administration.

END NOTES:

¹ TRAINEE is used as a generic term to mean any individual in training. Trainees may include, but may not be limited to: undergraduate and graduate students, postdoctoral fellows, residents, junior colleagues.

² DEPARTMENT HEAD is used as a generic term to mean the immediate administrator, which is normally a department chair, program director, center director, or a dean.

³ RESEARCH DIRECTOR is used as a generic term to mean any individual who is a dissertation advisor, laboratory director or research program director. The Principal Investigator on any grant/contract is the Research Director for the research program supported by that grant/contract.

APPENDIX

RECORDS RETENTION: Grants and Other Types Of Agreements

[NOTE: Retention of any specific record is controlled by the applicable requirement with the LONGEST retention requirement]

General Regulation:

See MCO Policy 01-037 (Records Management) for general information regarding records retention. Specific requirements for records retention of certain types of records related to extramural Grants and Contracts are outlined below.

Federal Requirements

OMB (Office of Management and Budget) Circular A-110 (Uniform Administrative Requirements for Grants and Agreements of Higher Education, Hospitals and Other Non-Profit Organizations). This regulation applies to all federally funded grants and other types of agreements.

Records must be retained for at least three (3) years from the date of the submission of the final expenditure report.

Specific Agencies (for example):

- 1) Health and Human Services: 45 CFR (Code of Federal Regulations) 74(D): Records must be retained for at least three (3) years from submission of last expenditure report.
- 2) US Department of Education: 34 CFR 74(A): Records must be retained for at least three (3) years from submission of last expenditure report.

State of Ohio Requirements

Records relating to awarded grants must be kept for the active year plus the previous five (5) years

Records relating to patents must be kept for the active year plus the previous six (6) years

Recruitment/search committee files for contract employees (including faculty) must be kept for three (3) years

Records and Reports: Clinical Trial Agreements

1) Food and Drug Administration: 21 CFR 312.62: In general, records must be retained for at least two (2) years following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, until two (2) years after the investigation is discontinued and FDA is notified, OR as agreed to in the contract with the sponsor governing the clinical trial.

2) Food and Drug Administration: 21 CFR 56.115: Regarding IRB records: Records required by this regulation shall be retained for at least three (3) years after completion of the research.

